# Complete Summary

## GUIDELINE TITLE

Mycobacterial infections.

## BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Mycobacterial infections. New York (NY): New York State Department of Health; 2006 Sep. 24 p. [10 references]

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Infectious complications associated with HIV infection: mycobacterial infections. New York (NY): New York State Department of Health; 2005 May. 20 p.

## ** REGULATORY ALERT **

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse (NGC)**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

## COMPLETE SUMMARY CONTENT

## SCOPE

### DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV)-associated mycobacterial infections:

- Tuberculosis (TB)
- *Mycobacterium avium* complex (MAC) infection
- Other uncommon mycobacterial infections

### GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

### CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine

### INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

### GUIDELINE OBJECTIVE(S)

To provide guidelines for the diagnosis, management, and prevention of human immunodeficiency virus (HIV)-associated mycobacterial infections

### TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients at risk for or with confirmed mycobacterial infections

### INTERVENTIONS AND PRACTICES CONSIDERED

#### Management of Tuberculosis (TB)

1. Chest x-ray
2. Acid-fast bacilli (AFB) staining of at least three sputum specimens collected on different days
3. Histopathology and special staining of other tissue specimens (e.g., blood, urine, stool, cerebrospinal fluid, pleural and pericardial fluid, biopsy specimens) if available
4. Enrolling patients into a directly observed therapy (DOT) program
5. Susceptibility testing for the 5 first-line anti-TB drugs
6. Treatment of non-drug-resistant active TB with isoniazid, rifampin, pyrazinamide, and ethambutol
7. Treatment of multidrug-resistant TB using three or more drugs to which the strain is susceptible
8. Follow-up during and after TB treatment including monitoring, patient education, repeat susceptibility testing, monthly weighing and vision tests
9. Management of latent TB infection:
    - 5 tuberculin unit (UT) purified protein derivative (PPD) at baseline and annually thereafter
    - Detailed history and physical examination
    - Chest x-ray
    - Treatment with isoniazid plus pyridoxine

**Management of *Mycobacterium avium* Complex (MAC) Infection and Mycobacterial infections other than TB or MAC**

1. Assessing symptoms and obtaining blood culture
2. Macrolide (clarithromycin or azithromycin) and ethambutol therapy
3. Chemoprophylaxis against MAC in HIV-infected patients with CD4 cell counts <50 cells/$mm^3$
4. Advice of an expert for management of mycobacterial infections other than TB or MAC

**Infection Control Issues**

1. Use of airborne precautions and specialized rooms
2. Use of a code-compliant AFB isolation room
3. Properly fitted disposable particular respirators for staff members
4. Criteria for discharging patients with TB from the hospital

### MAJOR OUTCOMES CONSIDERED

- Accuracy of diagnostic tests
- Effectiveness of treatment in terms of survival rate and relapse rate

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

### Quality of Evidence for Recommendation

I. Evidence from one or more properly randomized, controlled trial
II. Evidence from one or more well-designed clinical trial without randomization; from cohort or case-controlled studies
III. Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

External Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The quality of evidence (I-III) is defined at the end of the "Major Recommendations" field.

#### Diagnosis of Tuberculosis (TB) Disease

Clinicians should obtain a series of at least three sputum specimens collected on different days to establish the diagnosis. When diagnosis cannot be established from three expectorated sputum samples, induced sputum or bronchoscopy may be necessary. (**I**)

Clinicians should send sputum specimens from human immunodeficiency virus (HIV)-infected patients suspected of having TB to a microbiology laboratory for acid-fast bacilli (AFB) staining and mycobacterial cultures. Sputum should be induced when an expectorated specimen cannot be produced. Results of AFB sputum smears should be available within 24 hours of obtaining a specimen. (**I**)

In addition to sending specimens to the microbiology laboratory, clinicians should send other tissue specimens (e.g., blood, urine, stool, cerebrospinal fluid, pleural and pericardial fluid, biopsy specimens), when available, to the anatomic pathology laboratory for histopathology and special staining (i.e., AFB stains). (**I**)

**Key Points**:

- Pulmonary TB should be included in the differential diagnosis of any HIV-infected patient with unexplained fever and cough.
- Both pulmonary and extrapulmonary TB should be included in the differential diagnosis of any HIV-infected patient with otherwise unexplained fever, weight loss, and/or signs and symptoms of systemic or localized infection.

**Directly Observed Therapy**

Clinicians should enroll all HIV-infected patients with TB into a directly observed therapy (DOT) program. (**I**) For patients who refuse DOT, clinicians should carefully monitor therapy. (**III**)

**Key Point**:

Most patients will adhere to anti-TB therapy when adequate social services and either home- or field-based DOT are provided.

**Treatment of Non-Drug-Resistant Active TB Disease**

HIV-infected patients with TB should ideally be treated in consultation with an HIV Specialist who has expertise in treating TB. (**I**)

Even if the results of definitive cultures are not yet available, anti-TB chemotherapy should be initiated in HIV-infected patients when TB is suspected and AFB are present in clinical specimens (see Figure 1 in the original guideline document). A macrolide should be added for *Mycobacterium avium* complex (MAC) coverage if the patient has a CD4 count <50 cells/$mm^3$, pending culture results. (**III**)

Rifapentine should not be used in HIV-infected patients because of its association with acquired rifamycin resistance in these patients. (**I**)

Streptomycin should not be used in pregnant women because it has been documented to cause congenital deafness in the human fetus. (**I**)

In addition to ordering AFB smears and cultures, clinicians should order susceptibility testing to the five first-line anti-TB agents (isoniazid, rifampin, pyrazinamide, ethambutol, streptomycin) once *Mycobacterium tuberculosis* is identified. (**III**)

For patients with drug-susceptible TB, clinicians should prescribe treatment for a minimum of 6 months. In patients with a delayed response (failure to convert to sterile cultures after 2 months of anti-TB therapy), treatment should be prolonged

to either 9 months, or 4 months after culture conversion, whichever is greater. (**II**)

**Treatment of Multidrug-Resistant TB (MDRTB)**

When treating patients with TB, clinicians should consider the possibility of drug-resistant TB, including MDRTB, in the following populations: (**III**)

- Patients who have a previous history of treatment for TB
- Patients who have been exposed to an individual with resistant TB
- Patients who fail to exhibit the expected clinical or mycobacteriologic response to a standard four-drug anti-TB regimen
- Patients who have lived in a country with a high rate of resistant TB

In consultation with an HIV Specialist who has experience treating MDRTB, clinicians should prescribe a regimen of three or more drugs to which the strain is susceptible, if possible (see Figure 2 in the original guideline document). An injectable drug should be used for at least 6 months. (**I**)

Clinicians should add at least two new drugs to a treatment regimen that is failing. (**I**) A regimen is considered failing when the patient is not improving clinically within 2 weeks of the collection of the initial sputum samples, or the AFB smears and cultures are positive after 4 months of therapy.

For patients with TB resistant only to isoniazid, clinicians should prescribe a three-drug regimen of rifampin, ethambutol, and pyrazinamide given for 6 to 9 months, or 6 months after culture conversion, whichever is longer. (**I**)

**Considerations for Administering Simultaneous Highly Active Antiretroviral Therapy (HAART) and Anti-TB Therapy**

For HIV-infected antiretroviral (ARV)-naïve patients with CD4 cell counts >200 cells/$mm^3$, clinicians should consider delaying HAART until a minimum of 2 to 6 months of a standard anti-TB regimen is completed. (**III**) For patients with CD4 counts <200 cells/$mm^3$, clinicians should initiate HAART 4 to 8 weeks after anti-TB medications are initiated. (**III**)

Clinicians should not use rifampin with indinavir, nelfinavir, lopinavir, saquinavir, amprenavir, or atazanavir, either alone or in dual protease inhibitor (PI) combinations using low-dose ritonavir (<200 mg twice daily).

When HAART cannot be delayed, clinicians should consider using rifampin or rifabutin with efavirenz or, if a PI is required, substituting rifabutin for rifampin. The rifabutin dose should be adjusted depending on which PI or non-nucleoside reverse transcriptase inhibitor (NNRTI) is used (see Appendix A in the original guideline document).

**Key Point**:

Rifabutin may be used with PIs. Although dose adjustments may be necessary, it is associated with fewer problematic drug interactions than rifampin (see Appendix A in the original guideline document).

**Follow-Up during and after Tuberculosis Treatment**

Clinicians should monitor patients receiving anti-TB chemotherapy monthly for response to treatment, adherence to treatment, and evaluation of medication toxicity. (**III**)

Clinicians should educate patients receiving anti-TB chemotherapy about the symptoms of hepatitis and should obtain serum liver enzyme levels, especially in patients with any one of the following: (**I**)

- Elevated baseline serum liver enzymes
- Symptoms suggestive of hepatitis such as anorexia
- Other risk factors for hepatitis, such as older age ($\geq$65 years), use of other potentially hepatotoxic drugs, alcoholism, or viral hepatitis

Clinicians should order expectorated or induced sputum monthly for both AFB smear and culture for patients who have been diagnosed with pulmonary TB and are receiving treatment, until documentation of culture conversion has occurred. (**III**)

For patients with culture-negative TB, a chest x-ray should be obtained at 2 months and at the end of treatment. (**III**)

Clinicians should obtain repeat susceptibility testing if cultures remain positive after 3 months of treatment or earlier if the patient's condition is worsening while receiving an apparently adequate regimen. (**III**)

Clinicians should weigh patients monthly and follow weight as an indication of clinical response to therapy.

Clinicians should perform monthly vision tests in patients receiving ethambutol. (**III**)

**Management of Latent TB Infection**

For HIV-infected patients without a history of TB or a positive tuberculin skin test (TST), clinicians should order a 5-tuberculin unit (TU) purified protein derivative (PPD) at the time of the initial evaluation and annually thereafter. (**I**) Induration of $\geq$5 mm is considered a positive test and an indication for treatment of latent TB infection (LTBI). (**I**)

Anergy testing is not recommended at the time of tuberculin skin testing. (**I**)

For HIV-infected patients with a new positive TST, clinicians should obtain a detailed history, perform a physical examination, and obtain a chest x-ray to determine whether active TB is present. (**I**)

HIV-infected persons with LTBI should receive treatment to prevent progression to TB disease; however, treatment for LTBI should not be initiated until active TB disease is excluded. (**III**) The preferred regimen for LTBI is 9 months of isoniazid 300 mg daily (or 900 mg twice weekly if directly observed) plus pyridoxine, 25 mg per day or 50 mg twice weekly, to prevent peripheral neuropathy. (**I**)

Clinicians should avoid using rifampin plus pyrazinamide to treat LTBI because of the risk of severe liver injury and death. (**I**) If there are no other alternatives, an expert in the management of TB should be consulted prior to use of this regimen. (**I**)

Directly observed therapy for latent TB infection should be offered to patients when it is available. (**I**)

**Infection Control Issues**

Clinicians should use airborne precautions and specialized rooms in situations that pose high risk for TB transmission, including sputum induction, bronchoscopy, and use of aerosolized pentamidine for prophylaxis of *Pneumocystis jirovecii* pneumonia (PCP). (**I**)

Clinicians should place any individual admitted to a hospital and suspected of having AFB smear-positive pulmonary or laryngeal tuberculosis in a code-compliant AFB isolation room until one of the following occurs: (**I**)

- The indicated therapy has been initiated and the patient has had a clinical and bacteriologic response to therapy (three consecutive negative AFB sputum smears)
- Disease due to *M. tuberculosis* has been excluded

Clinicians should not transfer patients receiving therapy for pulmonary TB to a non-isolation room until they have resolution of signs and symptoms (especially cough) and they have had three consecutive negative AFB sputum smears on different days. (**I**) Smear-positive patients should receive a minimum of 2 weeks of anti-TB therapy before additional AFB smears are obtained. (**III**)

Staff members who enter the rooms of, or who have contact with, smear-positive patients with TB should wear properly fitted disposable particulate respirators capable of filtering small (1-5 microns) aerosolized particles. Common surgical masks are not effective. (**I**)

Clinicians should not discharge patients with smear-positive pulmonary TB from the hospital unless they meet all of the following criteria: (**III**)

- Their symptoms and signs, especially the cough, are resolved or near resolution.
- They are receiving therapy to which the strain is known to be, or very likely to be, susceptible.
- They are highly likely to adhere to the prescribed course of anti-TB therapy (e.g., DOT).

- They are not being discharged to congregate living environments or households where immunocompromised people or young children live.

### *Mycobacterium avium* Complex Infections

*Diagnosis*

Clinicians should consider a diagnosis of disseminated MAC infection in any severely immunosuppressed patient with acquired immunodeficiency syndrome (AIDS) who presents with otherwise unexplained persistent fever, sweats, weight loss, and/or pancytopenia. (**III**)

Clinicians should obtain blood culture to diagnose disseminated MAC infection. (**I**) Sputum and stool cultures are generally not diagnostic of disease.

*Treatment*

Clinicians should treat all patients with disseminated MAC infection. (**I**) Treatment regimens should include at least two drugs to increase efficacy and prevent the emergence of resistance. (**I**)

Clinicians should include a macrolide antibiotic (either clarithromycin or azithromycin) and ethambutol in all regimens for treatment of disseminated MAC infection. (**I**)

The clinician should initiate effective antiretroviral therapy (ART) in HIV-infected patients with disseminated MAC infection who are not already receiving ART. (**I**)

A three-drug regimen against MAC should be considered for patients not able to be prescribed effective ART. (**II**)

*Prevention*

Clinicians should administer chemoprophylaxis against disseminated MAC to HIV-infected patients with CD4 cell counts <50 cells/$mm^3$. (**I**)

Clinicians should use one of the following regimens for primary prevention of disseminated MAC: (**I**)

- Clarithromycin 500 mg twice daily (bid)
- Azithromycin 1200 mg per week

If neither clarithromycin nor azithromycin are tolerated, rifabutin (300 mg each day) should be used as an alternative agent for primary prevention. (**III**)

Before initiating prophylaxis, clinicians should exclude disseminated MAC disease by clinical evaluation, which may include obtaining a blood culture. (**III**)

### Mycobacteria Other Than TB and MAC

When mycobacteria other than TB or MAC are isolated and implicated in infection, the clinician should seek the advice of an expert to aid in the management of uncommon infections. (**III**)

**Definitions**:

**Quality of Evidence for Recommendation**

I. Evidence from one or more properly randomized, controlled trial
II. Evidence from one or more well-designed clinical trial without randomization; from cohort or case-controlled studies
III. Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

### CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document for:

- Treatment of TB in HIV-Infected Patients
- Treatment of Drug-Resistant TB

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and prevention of mycobacterial infections in human immunodeficiency virus (HIV)-infected patients

### POTENTIAL HARMS

**Adverse Effects of Medications**

- *Rifampin/rifabutin*: rash, hepatitis, fever, thrombocytopenia, flu-like symptoms. In addition, rifampin has interactions with numerous medications including protease inhibitors, antifungal azoles, oral contraceptives, and methadone. (Refer to Appendix A in the original guideline document for information on rifampin dose adjustments)
- *Isoniazid*: rash, hepatic enzyme elevation, hepatitis, peripheral neuropathy, mild central nervous system effects
- *Pyrazinamide*: gastrointestinal upset, hepatitis, rash, arthralgias, hyperuricemia, gout (rare)
- *Ethambutol*: optic neuritis, decreased visual acuity, rash

Refer to Table 2 in the original guideline document for information on side effects of streptomycin, levofloxacin, cycloserine, ethionamide and other anti-tuberculosis drugs and to Appendix A in the original guideline document for more information on drug interactions between anti-tuberculosis and antiretroviral drugs.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

- Simultaneous initiation of anti-tuberculosis (TB) therapy and highly active antiretroviral therapy (HAART) in antiretroviral-naïve patients should be avoided because the problems associated with complex interactions and overlapping toxicity of these agents may be overwhelming.
- Rifampin should not be used with indinavir, nelfinavir, lopinavir, saquinavir, amprenavir, or atazanavir, either alone or in dual protease inhibitors (PI) combinations using low-dose ritonavir.
- Streptomycin should not be used in pregnant women because it has been documented to cause congenital deafness in the human fetus.
- Use of rifampin with saquinavir alone is contraindicated.
- Use of rifampin plus pyrazinamide to treat latent TB infection should be avoided because of the risk of severe liver injury and death.
- Rifapentine should not be used in HIV-infected patients because of its association with acquired rifamycin resistance in these patients.

Refer to Appendix A in the original guideline document for more information on contraindications.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

The guidelines in the "Treatment of Multidrug-Resistant TB (MDRTB)" section should be considered only as suggested regimens. Opinions vary about both the optimal drug regimens and the necessary duration of therapy. If there is any doubt about optimal therapy, expert consultation is advised.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

#### Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative, the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the NYSDOH Distribution Center for providers who lack internet access.

**Guidelines Implementation**

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AIDS Education and Training Centers (AETC). The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

**IMPLEMENTATION TOOLS**

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED**

Getting Better
Living with Illness
Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Mycobacterial infections. New York (NY): New York State Department of Health; 2006 Sep. 24 p. [10 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2005 May (revised 2006 Sep)

### GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

### SOURCE(S) OF FUNDING

New York State Department of Health

### GUIDELINE COMMITTEE

Medical Care Criteria Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Chair*: Jessica E Justman, MD, Columbia University, New York, New York

*Vice-Chair*: Barry S Zingman, MD, Montefiore Medical Center, Bronx, New York

*Members*: Judith A Aberg, MD, New York University School of Medicine, New York, New York; Bruce D Agins, MD, MPH, New York State Department of Health AIDS Institute, New York, New York; Barbara H Chaffee, MD, MPH, Binghamton Family Care Center, Binghamton, New York; Steven M Fine, MD, PhD, University of Rochester Medical Center, Rochester, New York; Barbara E Johnston, MD, Saint Vincent's-Manhattan Comprehensive HIV Center, New York, New York; Jason M Leider, MD, PhD, North Bronx Healthcare Network of Jacobi and North Central

Bronx Hospitals, Bronx, New York; Joseph P McGowan, MD, FACP, Center for AIDS Research & Treatment, North Shore University Hospital, Manhasset, New York; Samuel T Merrick, MD, New York-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York; Rona M Vail, MD, Callen-Lorde Community Health Center, New York, New York

*Liaisons*: Sheldon T Brown, MD, Liaison to the Department of Veterans Affairs Medical Center, Bronx Veteran Affairs Medical Center, Bronx, New York; Douglas G Fish, MD, Liaison to the New York State Department of Corrections, Albany Medical College; Albany, New York; Peter G Gordon, MD, Liaison to the HIV Quality of Care Advisory Committee, Columbia University College of Physicians and Surgeons, New York, New York; Fabienne Laraque, MD, MPH, Liaison to the New York City Department of Health and Mental Hygiene, Treatment and Housing Bureau of HIV/AIDS Prevention and Control, New York, New York; Joseph R Masci, MD, Liaison to New York City Health and Hospitals Corporation, Elmhurst Hospital Center; Elmhurst, New York

*AIDS Institute Staff Physician*: Charles J Gonzalez, MD, New York State Department of Health AIDS Institute, New York, New York

*Principal Investigator*: John G Bartlett, MD, The Johns Hopkins University, Baltimore, Maryland

*Principal Contributor*: Judith A. Aberg, MD, New York University School of Medicine, New York; Edward Telzak, MD, Bronx-Lebanon Hospital Center, Bronx

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Infectious complications associated with HIV infection: mycobacterial infections. New York (NY): New York State Department of Health; 2005 May. 20 p.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

## AVAILABILITY OF COMPANION DOCUMENTS

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI Institute on September 7, 2007. This NGC summary was updated by ECRI Institute on June 6, 2008. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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# DISCLAIMER

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Date Modified: 9/29/2008


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